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13. ABSTRACT ***(Maximum 200 Words)*** Implementation of the Vietnam Head Injury Study Phase III (VHIS3) has begun. In Oct 2002, an understanding was reached with the National Naval Medical Center (NNMC), and the necessary administrative and testing space has been obtained. We received approval for a funding supplement to cover the costs of the CT and EEG procedures and reports. We have hired all study staff. A protocol to study subjects at NNMC has been approved. The test battery to be administered to the participants has been finalized, a database created, eligible participants have been contacted to send an updated address to us with good compliance, programmatic procedures for the evaluation week have been developed, equipment purchased, and staff is being trained. Thus, we are only awaiting final protocol approvals and inter-agency cooperative agreement signatures before we begin to directly contact and invited participants to be studied.

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Introduction

This report summarizes events for the period September 24, 2002 to September 23, 2003 in the implementation of the Vietnam Head Injury Study - Phase III: A 30-Year Post-Injury Follow-up Study, funded by the US Army Medical Research and Material Command, under grant no. DAMD17-01-1-0675.

Narrative

The implementation of the Vietnam Head Injury Study - Phase III (VHIS-P3) was delayed during the previous year as negotiations with the National Naval Medical Center, Bethesda (NNMC) continued. Originally, NNMC assured The Henry M Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF) that a Memorandum of Understanding (MOU) was the preferred method for transfer of grant funds. However, after HJF and NNMC agreed on a final version of the MOU, the Department of the Navy, Bureau of Medicine and Surgery (BUMED) rejected the MOU as an, "inappropriate vehicle" and mandated that NNMC and HJF enter into a Cooperative Research and Development Agreement (CRADA). Since Dr. Grafman's primary affiliation is with the National Institute for Neurological Disorders and Stroke (NINDS) at the National Institutes of Health (NIH), and two government agencies are unable to enter into a CRADA, discussions took some time to clarify the appropriate instruments for agreements between NNMC, NIH and HJF. The result was the requirement of separate contracts: a CRADA between NNMC and HJF and a Confidential Disclosure Agreement (CDA) between NNMC and NIH to cover data transfer rights. The CRADA has been approved by HJF and is currently under review at the NNMC. The CDA has been drafted and is awaiting approval by the NNMC.

Although a meeting with Admiral Donald C. Arthur in January 2003 secured verbal Command Support for this study, the deployment of the USS Comfort and onset of Operation Iraqi Freedom hampered progress on many levels (occupation of space, legal contracts, delineation of responsibilities) as NNMC hospital and support staff significantly decreased during the first half of 2003. NNMC staffing has now returned to pre-war levels.

Although an understanding with NNMC regarding allocation of space was reached in October 2002, due to renovations, the offices necessary to carry out administrative functions were not ready for occupation until February 27, 2003. Furthermore, testing offices in the main hospital were requested to be ready by June 1, 2003 and, because of inadequate ITS resources, actual occupation was not feasible until mid-July 2003. The VHIS-P3 staff currently is occupying all administrative and testing offices.

On November 25, 2002, the study coordinator for the project began. To date all staff have been hired. All testing equipment (hardware, software, supplies) and office machines have been purchased. All mechanisms for transportation, lodging, and meals to be provided to VHIS-P3 participants have been established. The complete testing battery has been formalized and research assistants are being trained to provide support for the participants, administer all the tests, score them, and enter the data into a format for a database. We are currently on target to begin patient testing in January 2004.

The protocol to study VHIS-P3 subjects at NNMC was submitted to their Institutional Review Board in March 2003. Approval from the NNMC IRB was granted in May 2003; however, due to Dr. Grafman's employment at NINDS/NIH, NNMC mandated a Scientific Peer Review by that Institute. Peer approval was granted in August 2003. The NINDS IRB then entered into an agreement with the NNMC IRB in early September to rely upon the NNMC IRB for the protection of human subjects. Subsequently, the protocol was delivered to USAMRAA for their review and approval on September 17, 2003.

Since NNMC was unable to provide computed tomography brain scans (to measure the size and location of brain damage) and EEGs (brain electrical activity recording to evaluate patients for seizures) without charge, a formal request for a funding supplement to this award to cover the costs of the CT and EEG procedures and reports was made of the Army in November 2002. These funds were awarded in March 2003. A meeting with the Head of the NNMC Department of Radiology, CAPT Duncan Barlow, MD, in June 2003,confirmed their capability to perform the Phase 3 scans at study specifications. The Walter Reed Army Medical Center (WRAMC), site of the VHIS- Phase 2, has agreed to transfer the original Phase 2 CT scans for use (comparison) by the NNMC Department of Radiology.

After receiving permission from the Vice Acting Chair of the Human Subjects Research Review Board (HSRRB) to contact subjects who participated in the 1981-85 study (Phase 2) for confirmation of contact information (address and telephone number), the Veterans Administration (VA) Privacy Division forwarded the NNMC approved VHIS-P3 Confirmation of Information Request. All letters were sent to the Phase 2 veterans and controls from August 8 to September 15, 2003. Currently, 268 individuals have replied and more continue to respond daily.

Key Research Accomplishments

- Creation of the VHIS-P3 computer database: includes over 2,500 data points.
- Development of complete evaluation and test battery, test software, forms, and task administrative procedures.

Reportable Outcomes

- Phase 2 Veterans:
  Alive: 484 **256 have responded
  Deceased with permission to follow up: 21
  Deceased without permission to follow up: 15

- Phase 2 Controls:
  Total: 85 **12 have responded